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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,192	12/05/2006	Vega Masignani	PP020009.0003	8434

27476 7590 07/13/2010

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
07/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,192	MASIGNANI, VEGA	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5-10 and 12-27* is/are pending in the application.

4a) Of the above claim(s) *15 and 17-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5-10,12-14 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the Restriction requirement filed in March 1, 2010 is acknowledged. Applicant's election of Group I with traverse, claims 1-10, 12-14 and 16 is acknowledged.

The traversal is on the grounds that Groups I-VI are believed to be so linked as to form a single general inventive concept. Applicant urges that NCBI Accession No. Q8YAQ1 does not disclose proteins of the claimed invention in view of Applicant's amendment filed March 1, 2010.

Applicant urges that all claims share a common special technical feature that is not taught in the prior art.

These arguments have been fully considered but are not found to be persuasive for the reasons below: Lack of unity exists when a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features". The claimed invention is drawn to a protein consisting of the amino acid sequence of SEQ ID NO.1 with one or more mutations that reduce or eliminate ADP-ribosylating activity of the protein. A special technical feature is defined as a contribution which each of the inventions, considered as a whole, makes over the prior art. Group I lacks novelty under PCT Article 33(2) as being anticipated by Glaser et al disclose proteins that are variants of SEQ ID No.1. Glaser et al *(Science Vol. 294, October 26, 2001, p. 849-852).*

teach a polypeptide (lin0059) that is 65.6% identical to SEQ ID NO.1.

Therefore, Group I is the main invention in this application and it lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

2. Claims 1, 4, 11 and 28 have been canceled. Claims 2, 8, 15, 16, 17, 18 and 25 have been amended.

Claims 15 and 17-27 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 1, 2010.

Claims 2-3, 5-10, 12-14 and 16 are under examination.

Claim Objection

3. Claim 7 recites the phrase " listed in Table 1". See MPEP section 2173.05(s) Reference to Figures or Tables in the claims should be removed where possible; claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609

(Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m). Appropriate correction is required.

Specification Objection

4. The listing of references in the specification, pages 39-41 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Sequence Compliance

5. This application contains sequence disclosures, see Drawings for example. Figure 1 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.21(a)(1) and (a) (2). The amino acid sequence set forth at paragraph [0162] which is identified by a sequence identifier, e.g. SEQ ID NO. is not accompanied by a Computer Readable Form (CRF), a paper or electronic copy of the sequence and a statement indicating that the CRF and the paper copy are the same. Therefore, this application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 for the reasons(s) set forth on the attached Notice To Comply With

Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action should include both compliance with the sequences and a response to the Office action set forth below. Failure to fully comply with ***both*** these requirements in the time period set forth in this Office action will be held non-responsive.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

6. The claimed invention is directed to non-statutory subject matter. Independent claim 2 recites " …a protein…". The claims reads on a product of nature. Applicant can obviate this rejection by amending the claim so that it recites "a purified or isolated protein". Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2-3, 5-6,8-10, 12-14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to a protein consisting of the amino acid sequence of SEQ ID NO:1 with one or more mutations that reduce or eliminate ADP-ribosylating activity of the protein. The claimed invention encompasses any addition, deletions or substitution along the amino acid sequence as set in SEQ ID NO. 1.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the claimed genus of polypeptides, Applicant must adequately describe the antigenic determinants or the amino acids that are required for the recited ADP-ribosylating activity as recited in the claims.

The specification, however, does not disclose distinguishing and identifying features of a representative number of members of the genus of polypeptides to which the claims are drawn, such as a correlation between the structure of the immunoepitope and function so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of polypeptides. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or with which other amino acids, the non-essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. The specification fails to adequately describe at least a substantial number of members of the claimed genus of polypeptides capable of being used for a therapeutic purpose.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.
The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that

Applicant was in possession of the claimed invention at the time the application was filed.

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. *(Nature Biotechnology 7: 936-937, 1999*), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of polypeptides. Consequently, because the art is unpredictable, in accordance with the Guidelines, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of polypeptides to which the claims refer. Hence, only an polypeptide with a sequence comprising of SEQ ID NO:1 meets the written description requirements.

Scope of Enablement

8. Claims 2-3, 5-6,8-10, 12-14 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising SEQ ID NO: 1, does not reasonably provide enablement for variants or fragments of the polypeptide set forth in SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Independent claim 2 is drawn to a protein consisting of the amino acid sequence of SEQ ID NO:1, with one or mutations that reduce or eliminate ADP-ribosylating activity of the protein.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

The rejected claims are drawn to a protein consisting of the amino acid sequence of SEQ ID NO:1 with one or more mutations that reduce or eliminate ADP-ribosylating activity of the protein. The claimed invention encompasses any addition, deletions or substitution along the amino acid sequence as set in SEQ ID NO. 1.

While the skill in the art of immunology is high, to date, prediction of a specific immune response for any given composition is quite unpredictable. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology. Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al *(Science, 1990, 257:1306-1310)* teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Additionally, as evidenced by Greenspan et al. *(Nature Biotechnology 7: 936-937, 1999),* defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here

the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. This constitutes undue experimentation. Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of a given immune reaction, the specification, as filed, does not provide enablement for polypeptides which reduce or eliminate ADP-ribosylating activity other than those comprising polypeptides with the sequence comprising SEQ ID NO: 1.

The claims of the instant application is drawn to fragments and variants of SEQ ID NO.1. There is no guidance provided in the specification as how one would begin to choose these fragments or variants. The specification does not support the broad scope of the claims, which encompass all modifications and fragments because the specification does not disclose the following:

- the general tolerance to modification and extent of such tolerance;
- specific positions and regions of sequence(s) which can be predictably modified and which regions are critical;
- what fragments or variants, if any, can be made which the retain the biological activity if the intact protein; and
- the specification provide essentially no guidance as to which of the essentially infinite possible choice is likely to be successful.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are fragments or variants of SEQ ID NO. 1 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

The Applicant has not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of additions, deletions or substitutions and fragments of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the protein's structure and still maintain activity is unpredictable and the experimentation left those skilled in the art is unnecessarily and improperly, extensive and undue. See Amgen Inc v Chugai Pharmaceutical Co Ltd. 927 F 2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Exparte Forman, 230 U.S. P.Q. 546(Bd. Pat=. App & int. 1986).

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the claimed

invention commensurate in scope with the claims. In view of all of the above, all polypeptides encompassed by the claimed invention do not satisfy the requirements of 35 U.S.C. 112 first paragraph.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by Glaser et al *(Science Vol. 294, October 26, 2001, p. 849-852).*

Glaser et al teach a polypeptide that is a functional variant of SEQ ID No.1. Glaser et al teach a polypeptide (lin0059) that is 65.6% identical to SEQ ID NO.1.

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  Query Match             65.6%;  Score 2017;  DB 2;  Length 577;
  Best Local Similarity   82.3%;
  Matches  408;  Conservative   23;  Mismatches   35;  Indels   30;  Gaps
7;

Qy          1 MKEVNYREDDWREAKSALAPFAAANWVGGLFNNLEKVSKNMEEAEEDVQELDSDHAISFQ 60
              ||||||||||||||||||||||||||||||||||||||||||||||:||||||| |||||
Db          1 MKEVNYREDDWREAKSALAPFAAANWVGGLFNNLEKVSKNMEEAEEDIQELDSDRAISFQ 60

Qy         61 HTNYRGKYSAIEDDLMVLYKFSCHAGEKMETLVDQPFYEKLDAFVDGMQDLSISTYSTTN
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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120

Qy        121 RIGAKSKQTYTTTSGGS-QVIESIKEGATIEDLMNGDNFYANQMQLQYRDWQRANPDQDV
179
              |||||||||| :: |   |||||:|: ||||||:||||||||||||||||||||:|||
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180
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Qy        180 SKKDFQMGMLHSRAFEYKSIKDEQQEKEFWVNIVATVVIVGVSIFCPPAGLALAVGYGSL
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Qy        240 EAGSAISGKDWVSGRELSTEERALRGGLALLDIVPGVKALSTGAKAASAGSKLVRVGDNV
299

Db        241 EAGSAISGKDWVSGRELSTEERALRGGLALLDIVPGVKALSTGAKAASAGSKLVRVGDNI
300

Qy        300 LAGSKNVGKGTIDNGIQAGKQAMDLRLANAKKVSEAVQKKLTKDLDDIGTMAKTIQNKTK
359

Db        301 LVGSKNVGKGTIDNGIQAGKQAMDLRLANAKKVSEAVQKKLTKDLDDISTMAKTIQNKTK
360

Qy        360 ETFTLPPREQLAFARGGSIPEQSATGAAAIAAKKKLKDIMQNMDNLNVKGGGKDDIIE--
417

Db        361 ETFTLPPREQIAFAGGGSIPEQSAAGAASIAAKKKLKDIMQNMDNLNVKGGGKAGIIEGA
420

Qy        418 QNKSLKFTSLE---ESEKWGIDGFSVWRNSLSSREIQAIRDYTDIW---HYGNM------
465

Db        421 ENSGKYLDDIEIPDNMKKWDYP---------PSKEL--FKKYEEVYKNPKYYNQETGAIN
469

Qy        466 ----NGYLRGSVEKLA 477

Db        470 WPPNNGFIGETHERLA 485
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Glaser et al anticipate the claimed invention.

Status of Claims

10. No claims allowed.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Primary Examiner, Art Unit 1645
June 6, 2010